Attorney Docket No.: **INT-0004**
Inventors: **Mattern et al.**
Serial No.: **10/002,653**
Filing Date: **October 19, 2001**
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In the claims:

Please add the following new claim:

13. A composition comprising collagen and glycosaminoglycan cross-linked at a density which stabilizes the composition toward electron beam radiation while retaining characteristics of the composition to function as a matrix or scaffold to support tissue ingrowth.

REMARKS

Claims 1-12 are pending in the instant application. New claim 13 has been added. Support for this claim is provided in the specification at page 6, lines 20-23, page 18, lines 16-22 and page 19, lines 19-22. Thus, no new matter has been added and entry is respectfully requested.

Claims 1-12 have been subjected to a Restriction Requirement as follows:

Group I, claims 1-4, drawn to a composition or to a matrix or scaffold comprising the same, classified in class 435, subclass 395;

Group II, claims 5-11, drawn to a production method, classified in class 264, subclass 494; and

Group III, claim 12, drawn to a method for regenerating

dermal or sub-dermal tissue, classified in class 623, subclass 15.12.

The Examiner suggests that these Groups are distinct. Specifically, with respect to Groups II and I, the Examiner has acknowledged their relationship as a process of making and a product made. However, the Examiner suggests that the product as claimed can be made by another and materially different process, such as one involving chemical sterilization, rather than electron beam radiation since limitations pertaining to biocompatability, flexibility, etc. are not imposed in claims 1-4.

With respect to Groups III and I, the Examiner has acknowledged their relationship as product and process of use. However, the Examiner suggests that the Groups are distinct because the product as claimed can be used in other parts of the body or for culturing cell *in vitro*.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully disagree with the Examiner's characterization of the claimed invention. Contrary to the Examiner's suggestion that limitations pertaining to biocompatability, flexibility, etc. are not imposed in claims 1-4, these claims clearly state that the composition retains

"characteristics to function as a matrix or scaffold following sterilization". A matrix or scaffold is defined at page 8, line 6-14 of the specification as :

> a construct of natural or synthetic biomaterials, particularly collagens and their derivatives that can be used in a composite with a glycosaminoglycan (GAG), which are used *in vivo* and *in vitro* as structural supports for cells and tissues, frameworks for tissue formation and regeneration, surfaces for cell contact, or delivery systems for therapeutics.

Further at page 9, line 24, through page 10, line 2 of the specification it is taught that:

> Characteristics of compositions of the present invention which are monitored to insure that a matrix or scaffold comprising the composition retains its functions as a structural support for cells and tissues, a framework for tissue formation and regeneration, a surface for cell contact, or a delivery system for therapeutics upon terminal sterilization include, but are not limited to, porosity, density, degradation resistance or residence time, melting temperatures, water absorption characteristics, surface properties, compressibility, tensile strength, stiffness, cytotoxicity, irritation and sensitization, systemic toxicity, cell adhesion properties, bacterial endotoxin contents and presence of degradation production such as gelatine.

Thus, claims 1-4, when read in light of the teachings of the specification, clearly impose limitations of biocompatability and flexibility on the claimed composition to retain "characteristics to function as a matrix or scaffold following sterilization".

Applicants also respectfully disagree with the Examiner's

suggestion that use of chemical sterilization is a materially different process for production of the claimed compositions. It is respectfully pointed that independent claim 5 of Group II is not drawn to a method wherein electron beam radiation is required for sterilization. Instead, claim 5 is drawn to a method for producing a composition which comprises cross-linking the collagen and glycosaminoglycan. As stated in claim 5, crosslinking is performed at a density which stabilizes the composition toward electron beam radiation while retaining characteristics of the composition to function as a matrix or scaffold. However, this claim is in no way limited to electron beam radiation as the sterilization means.

Accordingly, the Examiner's reasoning for restriction of Groups I and II, because "the product as claimed can be made by another and materially different process, such as one involving chemical sterilization, rather than electron beam radiation" and "limitations pertaining to biocompatability, flexibility, etc. are not imposed in claims 1-4" is based upon an improper characterization of the claimed invention and thus is flawed.

MPEP § 803 makes clear that for a Restriction Requirement to be proper, two criteria must be met. The inventions must be

independent or distinct; and there must be serious burden on the Examiner if Restriction is not required. The Examiner has acknowledged the relationship of Groups I and II as product and process of production. Accordingly these Groups are not independent. Further, the Examiner has failed to provide adequate evidence establishing their distinctness based upon other methods for production thereof. Thus, this Restriction Requirement is improper, at least with respect to Groups I and II, as it fails to meet the first criteria for a proper Restriction Requirement.

Further, a proper search of the compositions of Group I would reveal any prior art relating to methods for their production. Accordingly, there does not appear to be any serious burden on the Examiner by maintaining at least Groups I and II in the prosecution of the instant application. Thus, this Restriction Requirement is also improper as failing to meet the second criteria for proper restriction.

Reconsideration and withdrawal of this Restriction Requirement is therefore respectfully requested.

However, in an earnest effort to advance the prosecution,

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Applicants elect group I, claims 1-4 and new claim 13, with traverse.

Applicants believe that this is a complete response to the Office Action of record.

Respectfully submitted,

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